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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
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09/027,821 02/23/98 CHASTAIN

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| EXAMINER |
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QM41/0201

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| PART UNIT | PAPER NUMBER |
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3737
DATE MAILED:

02/01/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 2/23/98

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-26 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1, 3-5, 13, 14, 16, AND 17 is/are rejected.
☒ Claim(s) 2, 6-12, 15, AND 18-26 is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☒ The drawing(s) filed on 2/23/98 is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 4
☐ Interview Summary, PTO-413
☒ Notice of Draftsperson's Patent Drawing Review, PTO-948 - SUBSTITUTE
☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

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DETAILED ACTION

Information Disclosure Statement

1. Acknowledgment is made of applicant's Information Disclosure Statement (PTO-1449) which was received by the Office on May 21, 1998. This document has been made of record in the file as Paper No.4.

Drawings

2. This application has been filed with informal drawings which are acceptable for examination purposes only.
3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "plurality additional of electrodes" in claim 14 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Claim Objections

4. Claims 7 and 8 are objected to under 37 CFR 1.75© as being in improper multiple dependent form:

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-Multiple dependent claim 7 depends from another multiple dependent claim -- claim 6.

-Claim 8 fails to refer to its depending claims in the alternative. To overcome this problem, the Examiner suggests substituting the language "claim 2 or 3" or "any one of claims 2 and 3" for the words "claims 2 and 3". See MPEP § 608.01(n).

Accordingly, claims 7 and 8 have not been further treated on the merits.

Claim Rejections - 35 USC § 112

5. Claims 3, 13, 14, 16, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the limitation "the series of peaks and valleys" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. To correct this deficiency, the Examiner suggests changing the dependency of the claim to depend from claim 2.

In regard to claim 13, the claim is indefinite. The phrase "a premolded polymer element(s)" is ambiguous since it is unclear whether or not one or more elements is being claimed. To clarify and overcome this rejection, the Examiner suggests substituting the phrase "at least one premolded polymer element".

In regard to claim 14, the claim is also indefinite. The language "plurality additional of electrodes" is confusing and appears to be a typographical error. To overcome this rejection, the Examiner suggests re-writing this phrase to read: "plurality of additional electrodes".

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In regard to claims 16 and 17, the claims are indefinite in that, as written, no positive structure is recited. To overcome this rejection, the Examiner suggests replacing the word "is" with "comprises" in both claims.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

7. Claims 1, 4, and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Swoyer '445.

The Swoyer '445 patent describes a cardiac lead for implantation in the coronary sinus vein (Fig.1) having all of applicant's claimed features including an "elongated flexible lead body" 3 whose distal end is attached to a tip electrode 20 and whose proximal end is attached to a connector assembly 4 having a terminal pin 6. The lead body contains a lumen (col.23, lines 55-56) housing an "elongated" inner conductor coil 11 (Fig.4) which electrically connects terminal pin 6 with tip electrode 20. The lead is pre-shaped with a "zone" consisting of two bends (52 and 54). During insertion into the body these bends are straightened out by the insertion of a stylet into the lumen (See Fig.3 and col.4, lines 10-33). Once properly located, the stylet is removed

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and the lead assumes its original bent shape. The Examiner considers these bends to perform the function of applicant's "discrete, longitudinally spaced points".

Allowable Subject Matter

8. Claims 3, 13, 16, and 17 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
9. Claims 2, 6, 9-12, 15, and 18-26 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
10. Since allowable subject matter has been indicated, applicant is encouraged to submit formal drawings in response to this Office action. The early submission of formal drawings will permit the Office to review the drawings for acceptability and to resolve any informalities remaining therein before the application is passed to issue. This will avoid possible delays in the issue process.

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Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The Giele '707, which describes an implantable pacing lead, is cited for its pertinent use of heat shrink tubing as a rigid supporting material.

The Stein '374 patent also describes an implantable cardiac lead which has uses the same shape concept as applicant to maintain itself within a patient's right ventricle. Unlike applicant's device, however, this device has been "optimized" for use in the patient's right ventricle (col.2, lines 5-8) and; therefore, could not be appropriately used within the coronary sinus.

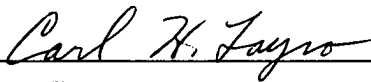
The Bowald et al '683 patent describes a set of pre-bent helical defibrillator leads which may be positioned along the walls of the coronary sinus and vein. Unlike applicant's device, however, the electrodes and pre-bent "zones" are one in the same; consequently, the applicant's condition that the "preformed shape" be located proximal to the "electrode" cannot be met.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (703) 308-3694. The examiner can normally be reached on M-F from 8:30 AM to 5:00 PM. A voice mail message may be left if desired.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef, can be reached on (703) 308-3256. The current fax number for this Group is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0858.



Carl H. Layno
Patent Examiner